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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,483	10/12/2000	Kevin H. Storm	P32685	9497

20462 7590 02/22/2006

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EXAMINER	
LEVY, NEIL S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/689,483	STORM ET AL.	
	Examiner	Art Unit	
	NEIL LEVY	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/04/2004 by PTO withdrawing from issue*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,18 and 69-218* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,18 and 69-218* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~3/24~~,12/10,1222/03. 3103
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Reciept is acknowledged of applicant's after final amendment, now entered, IDS's of 12/10/03,12/22/03 & 3/24/03.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim79-85, 93,138,144-146, 151, 154-155, 158, 159, 162-163, 166, 168, 173-178, 190-193, 208, 213, 218 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "foregoing" is indeterminate as to what constitutes the foregoing-claims 80-85 constitute multiple dependent claims.

<711> is not understood.

"Formulation VI" should not be in ( ). Claim 208 requires the method of 7-14 days. It is unclear if the method requires testing healthy volunteers everyday from the 7th through the 14th day, on what basis to begin counting to arrive at 7th day, or whether the method constitutes administering the composition every 12 hours for at least 7 but not more than 14 days, or administering once daily for 7 to 14 days, or determining that the method is repeated-administering the compostion, on the 7th day following we know not what.
Claim 138 has an unclear antecedent- the release phase & dosage units are not clearly identified.

Double Patenting

Claims 13,18,69-218 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-133 of U.S. Patent No.

6783773. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compositions of the patent are immediately envisioned as to be given as oral medications to humans to release in the aqueous environment of the g.i. tract effective amounts of antimicrobial to treat bacterial infections ; these are the instant method steps. The instant methods require administration of the identical compositions as claimed in the patent. Since the restriction in this case resulted in the election of methods & compositions, the patent claims provide prima facie obviousness.

Claims 13,18,69-218 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1-93 of U.S. Patent No. 6878386. Although the conflicting claims are not identical, they are not patentably distinct from each other because * Instant claim 204,205-use virtually the same as patent claim 25, 28, 40 with treatment of the instant respiratory infections of the same bugs (instant claim 207-207, 209-212, 214-217) at patent claim 26, 27 with the same plasma levels (patent claims 33-37, 43). The claims are not identical, as the clavulonate is not specified -yet falls between the ratios of the instant application.

Claims 13,18,69-218 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6136345 or 6358528 to Grimm et al , in view of PDR and Bax 6214359.. Although the conflicting claims are not identical, they are not patentably distinct from each other because Grimm shows the instant tablets, but not their use, except in general. PDR dileneates use, while Bax shows equivalence of amoxicillin forms.

.Claims 13,69-218 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-67 of copending Application No. 10/115700, now allowed. Although the conflicting claims are not identical, they are not patentably distinct from each other because '700 provides the instant dosage forms in essence, yet does not recite each limitation in anticipatory claim. However, one in the art would find it obvious to peruse all '700 claim, and arrive at the various modes of the invention as is instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 13, 70-172, 194-203 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 09/974596. Although the conflicting claims are not identical, they are not patentably distinct from each other because The compositions are useful as antibacterial dosage forms, immediately envisioned as daily administered (claim 22) to a patent in need thereof-the instant methods. Shown is the instant citric acid (claim 20), multiple dosage sachet (claim 13), gels in dosage intervals of about 12 hours (claim 1, 8-11 and 22)..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim13, 70-78, 97-102, 104-113, 123-126, 131, 132, 134, 135, 137, 138, 140-143, 150, 151, 153, 156, 157, 161, 165, 167, 169, 170, 195, 200-202 are rejected under 35 U.S.C. 102(e) as being anticipated by Grimmett et al 6136345 or 6358528

Grimmett shows the instant tablets (col 2, lines 23-59) with stearic acid, and the instant polymers (col 8) used (claims) as treatment for bacterial infections.

1. Claim13, 18, 70, 72-85, 97-102, 104-126, 131-141, 143, 144, 148, 156-158, 161, 162, 167, 170, 195, 199-203 are rejected under 35 U.S.C. 102(b) as being anticipated by Burch WO97/09042

See example 1-succinic acid, amoxicillin and clavulinate at instant (claim 1) ratio, used to treat *S. pneumoniae* (p. 8) results. Two tablets may be used in a unit dose (p. 4). Amoxicillin at 3500mg is shown (p. 4, top).

1. Claimz 13, 70, 72-78, 97-102, 104, 107, 109-112, 123, 126, 131-132, 134, 135, 137, 141-143, 156, 157, 170, 200-202 are * rejected under 35 U.S.C. 102(b) as being anticipated by Rivett et al WO96/04908

The instant ratios (p.2) in dual release unit dose tablets are shown, with stearic acid and (p.3) the instant polymers. Dosages are to 750 mg (p.5). Rapid-slow release forms are at pages 7-9, claim 9 ,for bacterial infection treatment claims1 4-16. The tablets (p.2) can contain separately, clavulinate and amoxicillin in both rapid and delayed release phases, and also in combination. Thus ratio of amoxicillin to amoxicillin and to amoxicillin and clavulinate in rapid to delayed forms are controllable by artisan and inclusive of the instant ranges of these ratios.

Claims 13,18,69-218 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mention et al WO98/35672

See claims-tablets of the instant invention are clearly anticipated-see pages 2, 3. Sodium amoxicillin, page 5 for forms and polymer, page 6 for stearic acid (lines 14-19). Granule size is at page 8, bottom; amoxicillin to clavulinate, penultimate paragraph. Tablets of 1000/125 mg are at page 10, bottom. Citric acid in effervescent tablets is at page 11, lines 23-32 at 5-30% of total tablet weight (p. 12) see example 11. Although all of the instant ratios claimed are not exemplified, they are seen as evident within the ranges taught by Mention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NEIL LEVY
Primary Examiner
Art Unit 1615

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